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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,832	12/30/2003	Heinz Redl	20695C-003420US	9378
44183	7590	10/31/2005	EXAMINER	
BAXTER HEALTHCARE CORPORATION ONE BAXTER PARKWAY MAIL STOP DF2-2E DEERFIELD, IL 60015			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/749,832

Applicant(s)

REDL ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8,12 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-33 is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8,12,24-28,34 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 6, 2005 has been entered.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-6, 8, 12, 24, 34, and 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,506,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '365 patent anticipate the instant claims.

3. The effective filing date of instant claims 1, 3-6, 8, 12, 24, 34, and 35 is deemed to be September 25, 2000, the filing date of grandparent application 09/669,240. Instant claims 1, 3-6, 8, 12, and 24 are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the '240 grandparent application because the '240 grandparent application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

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The effective filing date of instant claims 25-33 is deemed to be September 25, 2001, the filing date of parent application 09/963,156. Instant claims 25-33 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of grandparent application 09/669,240 because the '240 grandparent application, under the test of 35 U.S.C. 112, first paragraph, does not disclose a fibrin/fibrinogen-binding moiety which is a nucleic acid, does not disclose a substance capturing moiety which is a receptor or a part thereof, and does not disclose a pharmaceutically active substance which is a wound-healing substance.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 4-6, 8, 12, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by the Greenberg et al article (Analytical Biochem., Vol. 266, pages 153-164) as evidenced by Claremon et al (U.S. Patent No. 5,019,572). The Greenberg et al article teaches  $\alpha_v\beta_3$  integrin receptors covalently bound to a solid support. The  $\alpha_v\beta_3$  integrin receptors, in combination with the solid support, correspond to Applicants' claimed conjugate. While the  $\alpha_v\beta_3$  integrin receptors of the Greenberg et al article are not bound directly to one another, Applicants' claims do not exclude from their scope the presence of a linking agent. Further, Applicants do not define "conjugate" so as to exclude the Greenberg et al article's means for indirectly binding one  $\alpha_v\beta_3$  integrin receptor to another. Any  $\alpha_v\beta_3$  integrin receptor attached to the solid support of the

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Greenberg et al article corresponds to Applicants' fibrin/fibrinogen-binding moiety which can be an integrin (see, e.g., page 154, column 1, second paragraph, of the Greenberg et al article). Any other  $\alpha_v\beta_3$  integrin receptor attached to the solid support of the Greenberg et al article corresponds to Applicants' substance capturing moiety capable of reversibly binding to a pharmaceutically active substance, which can be a receptor. In the case of the Greenberg et al article, the other  $\alpha_v\beta_3$  integrin receptor covalently bound to a solid support is capable of binding to radioiodinated echistatin (see, e.g., page 155, column 2, last paragraph; page 156, column 1, first paragraph; and Figure 2). Claremon et al teach that echistatin is a platelet aggregation inhibitor (see column 4, lines 29-42), i.e. is a pharmaceutically active substance. The radioiodinated echistatin of the Greenberg et al article also corresponds to Applicants' pharmaceutically active substance which can be an imaging agent.

6. Claims 1, 3-6, 8, 12, 24, 34, and 35 are rejected under 35 U.S.C. 102(a) and (e) and claims 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gibbs et al (U.S. Patent No. 6,110,721). Gibbs et al teach NPs linked to anti-analyte antibodies, i.e. typically those directed against proteins participating in the blood clotting cascade, endothelial cell antigens, tumor antigens, and other cell surface macromolecules. The linkage can be covalent. Gibbs et al also teach NPs linked to analyte-binding receptors, i.e. typically LFA-1, VLA4, mac-1, I-CAM1, I-CAM2, I-CAM3, or V-CAM1. See column 33, lines 7-24. The NPs of Gibbs et al are preferably at least about 95% homologous to thrombin (see column 5, line 66 - column 6, line 5), and therefore correspond to a moiety derived from thrombin as claimed by Applicants. The proteins participating in the blood clotting cascade taught by Gibbs et al are plasma proteins and are wound healing substances.

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7. Applicant's arguments filed October 6, 2005 have been fully considered but they are not persuasive.

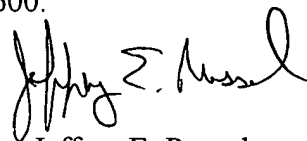
The anticipation rejection based upon the Greenberg et al article (Analytical Biochem., Vol. 266, pages 153-164) as evidenced by Claremon et al (U.S. Patent No. 5,019,572) is maintained. Applicants contend that because echistatin competitively inhibits the binding of  $\alpha_v\beta_3$  integrin receptor to native ligands, an  $\alpha_v\beta_3$  integrin receptor to which echistatin is bound will not also bind to another  $\alpha_v\beta_3$  integrin receptor, and the "tripartite interaction proposed by the Examiner does not exist". The examiner agrees that an  $\alpha_v\beta_3$  integrin receptor to which echistatin is bound will not bind with other ligands, but the examiner does not understand Applicants' reference to a "tripartite interaction". The rejection does not state or suggest that one  $\alpha_v\beta_3$  integrin receptor will bind to another  $\alpha_v\beta_3$  integrin receptor. The rejection does state that the  $\alpha_v\beta_3$  integrin receptors are linked to one another through the solid support and therefore form a conjugate as required by Applicants claims. Even if every  $\alpha_v\beta_3$  integrin receptor bound to the solid support is bound to echistatin in the Greenberg et al article, Applicants' claims are still met. Note that Applicants' claims permit the fibrin/fibrinogen-binding moiety and the substance capturing moiety to be chemically identical; and Applicants' claims permit both the fibrin/fibrinogen-binding moiety as well as the substance capturing moiety to be bound to a pharmaceutically active substance.

8. Claims 29-33 are allowed.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

October 27, 2005